Georgia Department of Community Health

State of Georgia
Request for Approval
Atlantic C-PORT Participation

FOR DEPARTMENT USE ONLY	
REQUEST NUMBER **CPORT**	*DATE STAMP*
Signed Original and 3 Copies _____	Fee Verified _____

GENERAL INFORMATION:

This Request Form is the required document that the Department reviews in the analysis and evaluation of requests in accordance with Ga. Comp. R. & Regs. r. 111-2-2-.21(3)(f)3.

1. Requesting Parties must submit a signed original and three copies of the signed form and the appropriate fee to help offset the costs to the Department in processing the request. The request fee of $500 shall be made payable to the "Department of Community Health" and shall be remitted by Certified Check or Money Order. Failure to submit the required fee and number of copies and the original will result in non-acceptance of the request.
2. This Request should be submitted to the Department concurrently with the submission of a request to participate in the trial to the Atlantic C-PORT team. The Requesting Party must attach as Exhibit 1 to this Request Form the documents submitted by the Requesting Party to the Atlantic C-PORT team for participation in the trial.

PLEASE COMPLETE THE FOLLOWING TABLE TO VERIFY PROPER SUBMISSION OF YOUR REQUEST	
REQUESTING PARTY NAME:	
1. Have you submitted an original signed in blue ink and provided 3 copies of this signed Determination Request form?	☐ **Yes** ☐ **No**
2. Have you submitted a Certified Check or Money Order made payable to "Department of Community Health" in the amount of $500.00?	☐ **Yes** ☐ **No**
3. Have you simultaneously submitted your request forms and documentation to the Atlantic C-PORT team to request approval for participation in the trial?	☐ **Yes** ☐ **No**
4. Have you attached your documentation and forms submitted to the Atlantic C-PORT team as Exhibit 1?	☐ **Yes** ☐ **No**

Submit the ***original and three copies*** of this form, the request fee and all additional documentation to:

Division of Health Planning
Atlantic C-PORT Participation Requests
Department of Community Health
2 Peachtree Street, NW, 34th Floor
Atlanta, Georgia 30303

Instructions

i. Please read all instructions and review this request form in its entirety before attempting to complete and submit it.

ii. This request form **must** be typewritten or completed and printed in this MS Word format. Handwritten requests and any additional responses will not be accepted.

iii. Throughout this request form, the following symbols are utilized for emphasis:

- 🗁 Emphasizes instances where supporting documentation is requested and required to be attached; and
- ☞ Emphasizes important instructions or notes that should be adhered to.

iv. Any exhibits or appendices to this form should be submitted on one-sided, 8 ½ by 11-inch paper only. Such exhibits or appendices should not be tabbed or otherwise separated from this main request form. If the Requesting Party wishes to label its exhibits or appendices when submitting multiple attachments, it should do so by numbering or lettering the exhibit or appendix on the first page of such attachment itself.

v. A signed original request form and three copies are required in addition to the appropriate fee of $500 for this request to be accepted by the Department. The fee shall be made payable by certified check or money order only to "Department of Community Health."

vi. The signed original request form and the three copies must be submitted on loose leaf, one-sided 8 ½ by 11-inch paper only. These documents must **not** be hole punched or bound by staple. The documents may be clipped or rubber banded to divide the original from each copy.

vii. The original and three copies must be submitted in a single envelope to the address indicated on the cover page of this form.

viii. Faxed or other electronically transmitted documents and information are not official and must be followed-up with the original documents for inclusion in the file.

1. Please complete the following information identifying the party requesting approval under Ga. Comp. R. & Regs. r. 111-2-2-.21(3)(f)3. The Contact Person should be an individual directly affiliated with the Requesting Party with authority to act on behalf of the legal entity. The Contact Person shall not be a consultant, law firm or attorney (unless a full-time employee of the Requesting Party).

REQUESTING PARTY		
Legal Entity:		
Address 1:		
Address 2:		
City:	State:	Zip:
County:		
CONTACT PERSON		
Name:	Title:	
Address 1:		
Address 2:		
City:	State:	Zip:
Phone:	Fax:	
E-mail:		

2. Does the Requesting Party have Legal Counsel to whom legal questions regarding this request may be addressed? ☐ **YES** ☐ **NO**

If **YES** ➔ Identify the legal counsel below. If **NO** ➔ Continue to the next question.

LEGAL COUNSEL		
Name:		
Firm:		
Address:		
City:	State:	Zip:
Phone:	Fax:	
E-mail:		

3. Did a Consultant prepare and/or provide information in this Request? ☐ **YES** ☐ **NO**

If **YES** ➔ Identify the Consultant below. If **NO** ➔ Continue to the next question.

CONSULTANT		
Name:		
Firm:		
Address:		
City:	State:	Zip:
Phone:	Fax:	
E-mail:		

4. Does the Requesting Party wish to designate and authorize an individual other than the Requesting Party Contact Person listed in response to Question 1 to act as the representative of the Requesting Party for purposes of this request?

☐ **YES** ☐ **NO**

If **YES** ➔ Please complete the information in the following table on the next page. By doing so, the Requesting Party authorizes the representative to submit this request; to provide the Department of Community Health with all information necessary for this request; to enter into agreements with the Department of Community Health in connection with this request; and to receive and respond, if applicable, to notices in matters relating to this request.

If **NO** ➔ Continue to the next question.

AUTHORIZED REPRESENTATIVE		
Name:		
Firm:		
Address:		
City:	State:	Zip:
Phone:	Fax:	
Email:		

☞ **NOTE:** *This authorization will remain in effect for this request until written notice of termination is sent to the Department of Community Health that references the specific request number. Any such termination must identify a new authorized representative. Also, if the authorized representative's contact information changes at any time, it is the responsibility of the Requesting Party to immediately notify the Department of Community Health, Division of Health Planning, of any such change.*

5. Does the Requesting Party have any lobbyist employed, retained, or affiliated with the Requesting Party directly or through its contact person or authorized representative?

☐ **YES** ☐ **NO**

If **YES** ➔ Please complete the information in the table below for each lobbyist employed, retained, or affiliated with the Requesting Party. Be sure to check the box indicating that the Lobbyist has been registered with the State Ethics Commission. Executive Order 10.01.03.01 and Rule 111-1-2-.03(2) require such registration.

If **NO** ➔ Continue to the next question.

LOBBYIST DISCLOSURE STATEMENT		
Name of Lobbyist	**Affiliation with Requesting Party**	**Registered with State Ethics Commission?**
	☐ Employed ☐ Other Affiliation	☐ Yes ☐ No
	☐ Employed ☐ Other Affiliation	☐ Yes ☐ No
	☐ Employed ☐ Other Affiliation	☐ Yes ☐ No
	☐ Employed ☐ Other Affiliation	☐ Yes ☐ No

6. 🗁 Please attach as **Exhibit 1** the materials, forms, and documentation being submitted to the Atlantic C-PORT trial administrator by the Requesting Party seeking to receive authorization to participate in the trial.

7. What unique contributions would the Requesting Party make to enhance knowledge in the area of percutaneous coronary intervention without on-site open-heart backup?

8. What functional barriers impeding access to prompt and adequate healthcare exist in the Requesting Party's service area that would justify allowing it to participate in the trial and perform percutaneous coronary intervention without on-site open-heart backup?

9. Explain the existing equipment that the Requesting Party currently has in its catheterization laboratory(ies) and any modifications that would be necessary to offer percutaneous coronary intervention. Include the name of the manufacturer of the equipment, the year manufactured, the year the equipment was acquired, and the amount of expenditures necessary to modify the equipment, if any.

10. What is the name of the nearest hospital offering open-heart surgery and how far is that hospital in miles and minutes? Does the Requesting Party have a transfer agreement with this or another hospital? If yes, 🗁 attach the agreement(s) to this Request Form as **Exhibit 2**.

11. Does the Requesting Party have 24-hour ambulance coverage? Provide a narrative description (e.g. relationship to facility, corporate structure, number of ambulances in each county within service area on a 24/7 basis, cardiac related equipment routinely on ambulances, training of ambulance personnel, access to air ambulance service) of the ambulance services available in the Requesting Party's service area. 🗁 In addition, please attach ambulance service agreement(s), if any, as **Exhibit 3**.

12. How many diagnostic cardiac catheterizations were performed at the Requesting Party's facility in Years 2001, 2002, 2003, and 2004?

2001	2002	2003	2004

13. In addition to the numbers in Question 12 above, please estimate the number of diagnostic cardiac catheterizations **not** performed at the Requesting Party's facility in Years 2001, 2002, 2003, and 2004 because a patient might have required an intervention and the patient was sent to a facility with open-heart backup instead.

2001	2002	2003	2004

Please explain any assumptions made in estimating these numbers:

14. Please enter the following data to estimate the number of primary percutaneous coronary interventions (for acute ST elevation MI patients) that the Requesting Party is likely capable of performing each year if approved.

Projected Primary Percutaneous Coronary Interventions	
(1) Year 2002 Doses of Thrombolytics for ST-Elevation MI **only**	
(2) Year 2003 Doses of Thrombolytics for ST-Elevation MI **only**	
(3) Year 2004 Doses of Thrombolytics for ST-Elevation MI **only**	
(4) Enter the Greater of lines (1), (2), or (3)	
(5) Estimate the number of ST elevation MI patients sent out from ED last year for primary PCI **without** antecedent thrombolytic therapy (**only** ST-Elevation MI)	
(6) Multiply line (4) by 1.2	
(7) Add lines (5) and (6)	

Please explain any assumptions made in estimating a number for Line (5) in the table above:

15. 🗁 Attach a list (e.g. CPT Codes or other description) of all therapeutic cardiac catheterizations not requiring open-heart backup performed at the Requesting Party's facility as **Exhibit 4**.

By signing below,

a) I hereby certify that the contained statements and all addenda, appendices, exhibits, or attachments hereto are true and complete to the best of my knowledge and belief and that I possess the authority to submit this request and bind the Requesting Party to promises made herein;

b) I understand that a representative of the Department of Community Health may make a direct request of the Requesting Party for additional information;

c) I further understand that if issued approval under Ga. Comp. R. & Regs. r. 111-2-2-.21(3)(f)3, the Requesting Party is bound to any representations that have been made within this Request and any and all supplemental information and Exhibits;

d) If awarded approval to participate in the research trial under Ga. Comp. R. & Regs. r. 111-2-2-.21(3)(f)3 and to perform percutaneous coronary intervention without on-site open-heart surgery backup as a participant in said trial, the Requesting Party covenants and promises the following:

1. That any such approval shall be only for the length of time that the Requesting Party is an active participant in said trial, except that in no case shall such approval be valid for a period in excess of three years from the date the Requesting Party performs the first percutaneous coronary intervention under such approval;

2. That under any such approval, percutaneous coronary intervention shall only be performed by the Requesting Party on patients who have been approved into the protocol of said trial by the Atlantic C-PORT team using the standard means adopted by said trial to approve such patients. The Requesting Party may not perform percutaneous coronary intervention on any other patient under any other circumstances unless otherwise permitted by law or regulation. The Department will rescind approval if the Requesting Party is found to have performed percutaneous coronary intervention on a patient not approved into the trial protocol;

3. To accurately report required data and outcomes into the trial's data management system and into the Department of Community Health's data management system within the time frames mandated by the trial. If such data and outcomes are not accurately and timely reported, any approval may be rescinded by the trial or by the Department;

4. To permit employees of the Department or its representatives unannounced and immediate access to the catherization lab, related areas and to all files, records, and documentations of any kind, including without limitation all medical records or others documentation relating to all patients who were treated in the catherization lab or upon whom a catherization was performed in the facility during the time of the trial.

e) I understand that the Requesting Party is required to provide a minimum of 100 percutaneous coronary interventions in the first year of participation and a minimum of 200 such interventions in each of the second and third years of participation. Any approval pursuant to 111-2-2-.21(3)(f)3 shall be subject to revocation if the Requesting Party fails to perform the minimum number of interventions. If the Requesting Party fails to meet the minimum of 200 interventions in the second year, in lieu of rescission of the approval, the Department may permit the Requesting Party to present a plan to attain 200 interventions the following year, provided that the Requesting Party has performed a minimum of 150 interventions in the second year;

f) I understand that the State will not award approval to participate in the trial unless and until the Atlantic C-PORT team has accepted the Requesting Party as a participant in the trial;

g) I further understand that the State will accept no more than 10 hospitals to participate in the trial; and

h) I affirm that if selected as a participant by the State and the Atlantic C-PORT team, if at any time the Requesting Party is expelled by or otherwise loses the approval of the Atlantic C-PORT team to continue participation, the approval of the State shall be automatically and simultaneously withdrawn without the right to appeal. The Requesting Party further acknowledges that the Department may withdraw its approval to participate at anytime, with or without cause; and upon such withdrawal, the Requesting Party shall immediately cease its participation in the trial without the right to appeal.

REQUESTING PARTY CERTIFICATION	
Signature of Authorized Signatory (BLUE INK ONLY):	
Name:	
Title:	*Date:*